IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSSETS

UNITED STATES OF AMERICA ex rel. Myo Tun, Relator,

STATE OF ARKANSAS ex rel. Myo Tun, Relator,

STATE OF CALIFORNIA ex rel. Myo Tun, Relator,

STATE OF COLORADO ex rel. Myo Tun, Relator,

STATE OF CONNECTICUT ex rel. Myo Tun, Relator,

STATE OF DELAWARE ex rel. Myo Tun, Relator,

DISTRICT OF COLUMBIA ex rel. Myo Tun, Relator,

STATE OF FLORIDA ex rel. Myo Tun, Relator,

STATE OF GEORGIA ex rel. Myo Tun, Relator,

STATE OF HAWAII ex rel. Myo Tun, Relator,

STATE OF ILLINOIS ex rel. Myo Tun, Relator,

STATE OF INDIANA ex rel. Myo Tun, Relator,

STATE OF LOUISIANA ex rel. Myo Tun, Relator,

STATE OF MARYLAND ex re. Myo Tun, Relator,

§

Civil Action No. 10cv11967 PBS

JURY TRIAL DEMAND RBC

FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730

DO NOT ENTER INTO PACER

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US ex rel Myo Tun v. St. Jude Medical, Incorporated

STATE OF MASSACHUSETTS ex rel. Myo Tun, Relator,	§
STATE OF MICHIGAN ex rel. Myo Tun, Relator,	§
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STATE OF NEW HAMPSHIRE ex rel. Myo Tun, Relator,	§
STATE OF NEW JERSEY ex rel. Myo Tun, Relator,	§
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STATE OF VIRGINIA ex rel. Myo Tun, Relator,	§
STATE OF WISCONSIN ex rel. Myo Tun,	§

FILED UNDER SEAL
US ex rel Myo Tun v. St. Jude Medical, Incorporated

Relator,	§
	§
vs.	§
	§
St. Jude Medical, Incorporated,	§
Defendant.	§

PLAINTIFF'S ORIGINAL COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729 *et seq.*, AND DEMAND FOR JURY TRIAL

1. This is an action by the United States of America brought by *qui tam* Relator Myo Tun to recover all damages, civil penalties, and other recoveries for violations of the Federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and the various States' false claims acts.

I. INTRODUCTION

2. This Complaint involves fraudulent schemes by Defendant St. Jude Medical, Incorporated ("St. Jude"), to increase sales revenue and market share of its cardiology surgical devices, implants, and instrumentation products. The aforementioned schemes involved the elaborate and systemic payment of kickbacks to physicians and medical centers throughout the United States in the form of illegal quid-quo pro bundling sales tactics and other improper incentives in order to induce those physicians, medical centers, and other health care providers to purchase and use St. Jude medical devices. St. Jude also engaged in off-label marketing practices for increased sales of its dual-chamber Implantable Cardiac Defibrillators ("ICDs") and cardiac resynchronization therapy devices (CRT-Ds).

3. Relator Myo Tun was a regional sales manager at St. Jude's Southern California cardiology division from January 2005 through January 2006. He supervised a team of sales representatives who primarily sold Vascular Closure Devices ("VCDs"), which are used to close artery puncture wounds after the insertion of catheters. Relator's team of sales representatives

sold other St. Jude cardiology products like the Angio-Seal STS and STS Plus, Venture wire control catheters, the Proxis system, Livewire steerable catheters, SpyGlass catheters, and the Premere patent foramen ovale (PFO) closure system. Relator together with his salespeople further collaborated with pacemaker, atrial fibrillation, and cardiac device sales divisions, together called the St. Jude's Cardiac Rhythm Management ("CRM") unit, to increase overall revenues for the company.

4. Because Relator worked in a managerial position at St. Jude, he gained independent and direct knowledge of St. Jude's policies and practices, amounting to schemes, which included instructing sales representatives to proffer kickbacks to physicians, hospitals, and surgical centers in order to encourage them to use and promote St. Jude vascular closure devices. These kickbacks were proffered in different ways but were all coordinated with one goal in mind: increased product sales.

5. As discussed in greater detail below, St. Jude provided illegal kickbacks by paying consultant fees to physicians who used St. Jude vascular closure devices to attend clinical advisory board meetings held at vacation destinations. St. Jude induced Key Opinion Leaders ("KOLs") in the cardiology field to use and promote their products by providing them with lavish dinners and entertainment. St. Jude would also pay for the physicians' travel expenses, meals, and entertainment at these events. Further, St. Jude funded and arranged continuing medical education ("CME") seminars where paid physicians gave lectures promoting the company's devices. St. Jude also made payments to physicians, hospitals, and surgical centers in the form of grants, fellowships, and proctor and preceptorship fees. St. Jude hired technicians and nurses to sell and promote their devices on a per diem basis. The large sums of money that St. Jude paid to physicians and other health care providers were intended only to increase the

purchase and use of St. Jude devices; targeted physicians were not being remunerated at fair market value for any services provided to St. Jude.

6. Relator also gained inside knowledge of a company-wide scheme in which health care providers were given illegal discounts and rebates for purposes of increasing St. Jude product market share. St. Jude aggressively pursued bundling purchase agreements with hospitals and physicians through its corporate sales and marketing strategy. Bundled purchases would include, for example, half-price or free catheter sheaths with the purchase of a pair of biopsy forceps. Other bundled arrangements included half-priced catheters, free Angio-Seal VCDs, Stasys patches, or credits to be applied toward future purchases in the form of rebates. Commonly, bundle arrangements were of VCD devices plus cardiac rhythm management devices, such as pacemakers and ICDs; or VSD devices plus cardiology vascular access devices.

7. St. Jude did not offer the discounts and rebates at issue to the government, which ultimately paid for St. Jude devices through programs like Medicare and Medicaid. Instead, St. Jude induced health care providers receiving Medicare and Medicaid reimbursement program money to make purchases through offers of free or deeply-discounted products from St. Jude and, in return, committed them to make future purchases. The bigger the purchases, the more profits health care providers stood to gain from St. Jude's discount and rebate program. Meanwhile, Medicare and Medicaid made periodic, pre-set reimbursement payments for medical devices well above the purchase price and in reliance on health care providers' participation agreements and other certifications made on Center for Medicare and Medicaid Services ("CMS") forms.

8. In the course of his employment, Relator also gained firsthand information that St. Jude promoted its ICD devices for uses that were not approved by the Food and Drug

Administration ("FDA"), selling the products off-label and without FDA approval. Relator additionally witnessed St. Jude salespeople ignore noted safety concerns regarding devices, teach health care administrators at hospitals and surgical centers to "upcode," pad, or increase reimbursement rates through CMS billing forms, and thus overbill Medicaid and Medicare.

II. PARTIES

9. St Jude is a public company categorized under Electromedical Equipment and headquartered at One St. Jude Medical Drive, Saint Paul, Minnesota. It was established in 1976 and incorporated in Minnesota. St. Jude is in the business of selling cardiac resynchronization therapy devices for heart failure, artificial pacemakers and ICDs for treating cardiac rhythm disorders, diagnostic and therapeutic electrophysiology catheters, introducers, catheters, and vascular closure devices for cardiology and vascular access, mechanical and tissue heart valves, and valve repair products. The company sells products in more than 100 countries and has over twenty operations and manufacturing facility worldwide. For fiscal year 2009, St. Jude reported net sales in the amount of $4.831 billion.

10. Relator Myo Tun is a serviceperson in the United States Armed Forces, a citizen of the United States, and a resident of California. Relator served on active duty in the United States Marine Corps from 1995 to 2000, and thereafter, joined the Marine Corps Reserves. As of 2009, Relator returned to active duty status and is currently a Major in the United States Marine Corps holding Sensitive Compartmented Information ("SCI") security clearance. Relator serves as an Intelligence Officer within the Operations Section at 1 Marine Expeditionary Force in Camp Pendleton, California.

11. Relator believes that there has been no public disclosure of the particular allegations set forth in this Complaint. As Relator worked directly and specifically as a St. Jude

sales manager, he is the original source of the facts and information set forth in this Complaint concerning the activities of Defendant. The facts averred herein are based upon the personal observations of Relator and documents in his possession.

12. From about January 2005 through January 2006, Relator was an employee of St. Jude, where he developed firsthand knowledge of the facts set forth herein. Acting as regional manager in the cardiology sales division, Relator's responsibilities included overseeing sales representatives and monitoring physician, hospital, and surgical center sales accounts in Southern California. While at St. Jude, Relator made sales calls, built rapport with doctors and hospital administrators, and developed and evaluated sales, marketing, and budget strategies. Relator also participated in nationwide corporate training and promotional events.

13. Relator has provided the United States and the States of Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Wisconsin, and the District of Columbia, a full disclosure of substantially all materials facts, as required by the False Claims Act, 31 U.S.C. § 3730(b)(2), and relevant state statutes.

III. JURISDICTION

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Under 31 U.S.C. § 3730(e), there has been no relevant public disclosure of the "allegations or transactions" in this Complaint.

15. Supplemental jurisdiction for Counts 6-34 arises under 28 U.S.C. § 1367, since these claims are so related to the federal claims that they form part of the same case or controversy under Article III of the U.S. Constitution.

16. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant can be found in, reside or transact, or has transacted business nationally and specifically within the District of Massachusetts.

17. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because the Defendant transacts or has transacted business in the District of Massachusetts. At all times relevant to this Complaint, Defendant regularly conducted substantial business within the District of Massachusetts and made significant sales within Massachusetts. In addition, the continuous statutory violations, as alleged herein, occurred in this district, as part of Defendant's nationwide scheme.

IV. FACTS

A. FDA Approval of Medical Devices

18. The approval of medical devices is governed by the Medical Device Amendments ("MDA"). Under the MDA, medical devices are categorized into three classes, based on the level of risk that they pose. 21 U.S.C. § 360c (a)(1). The pacemakers, ICDs, and cardiac resynchronization therapy devices (CRT-Ds) manufactured by St. Jude are "Class III" devices, as they "present a potential unreasonable risk of illness or injury" and are "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C).

19. In order for a Class III device to attain FDA approval for marketing and use, the device must undergo "premarket approval to provide reasonable assurance of its safety and effectiveness" before being marketed. *Id.* This premarket approval, or PMA, requires the manufacturer to submit a detailed application that contains full reports of all investigations of the safety and effectiveness of the device, a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information. 21 U.S.C. § 360e(c).

20. Once the FDA has approved a medical device through the PMA process, the applicant is required to comply with the standards in the PMA approval order. 21 C.F.R. § 814.80. Specifically, "[a] device may not be manufactured, packaged, stored, labeled, distributed or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." *Id.*

21. The Angio-Seal STS, Venture Wire Control, Proxis Flow Control System, Livewire steerable catheters, SpyGlass catheters, Premere patent foramen ovale closure system, and the Stasys patch are all Class II devices. Class II devices are approved through measures much less rigorous than Class III devices, pursuant to 21 U.S.C. § 360(k). That section imposes a limited form of review on every manufacturer intending to market a new device by requiring it to submit a "premarket notification" to the FDA (the process is also known as a "§ 510(k) process," after the number of the section in the original Act). If the FDA concludes on the basis of the § 510(k) notification that the device is "substantially equivalent" to a pre-existing device that was marketed prior to May 28, 1976, it can be marketed without further regulatory analysis.

Unlike the PMA review, which usually requires about 1,200 hours, the § 510(k) review is completed in an average of only 20 hours.

B. Coverage for Medical Devices

22. Medicare requires as a condition of coverage that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A); see also 42 C.F.R. § 411.15(k)(1). The Secretary of the United States Department of Health and Human Services is responsible for specifying those services that are covered under the "reasonable and necessary" standard. See 42 U.S.C. § 1395ff(a). An explanation of covered services for medical devices appears at 42 C.F.R. § 405.201 and Chapter 14 of the Medicare Benefit Policy Manual.

23. Pursuant to the Manual, Class III devices that may be covered under Medicare include those approved by the FDA through the PMA process. See Medicare Benefit Policy Manual, Ch. 14, section 10; see also 42 C.F.R. § 405.201. In addition, Medicare will cover some investigational devices under certain circumstances, depending on the category into which the device falls. *Id.* at section 20. "Category A" devices are those investigational devices believed to be in Class III for which an absolute risk has not been established (i.e., initial questions of safety and effectiveness have not been resolved). Class III devices are those that require premarket approval. 42 C.F.R. § 405.201(b). There is no Medicare coverage for "Category A" devices. *Id.* at section 30. "Category B" devices include those devices believed to be in Class III where the incremental risk is the primary risk in question (i.e. underlying questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Medicare may cover such devices "if they are considered reasonable and

necessary and if all other applicable Medicare coverage requirements are met." *Id.* at sections 20.2 and 30.

24. Medicare reimbursement determinations are generally made through "fiscal intermediaries" or contractors: private entities that process, review, and pay claims submitted by providers. See 42 U.S.C. § 1395h. These Medicare contractors are responsible for making coverage determinations on all FDA-approved Category B devices. In order for a Category B device to be covered, (1) the device must be used within the context of an FDA-approved clinical trial; (2) it must be used according to the clinical trial's approved patient protocols; (3) there may be an established national policy or local policy for similar FDA-approved devices; and (4) there may be policy/position papers or recommendations made by pertinent national or local specialty societies pertaining to its use. Medicare Benefit Policy Manual, Ch. 14, section 50.

25. In addition, CMS must use the FDA categorization of a device as a factor in making Medicare coverage decisions. 42 C.F.R. § 405.201(a). The FDA assigns a device as either Category A or Category B and notifies CMS when it notifies the manufacturer of the device, whether the device has been categorized as Category A or Category B. 42 C.F.R. § 405.203. Medicare contractors are bound by the statute, regulations, and all CMS administrative issuances, including all national coverage decisions. 42 C.F.R. § 405.211. Medicare contractors must also "consider whether any restrictions concerning . . . indications for use . . . have been placed on the device's use" when determining whether to provide reimbursement for a device. 42 C.F.R. § 405.211(c).

26. Thus, Medicare will not provide reimbursement for a medical device where the device indication is not approved by the FDA through a PMA process or where the indication is not classified as "Category B," meaning Medicare will not reimburse for an indication that is not

being investigated pursuant to an FDA-approved clinical trial and according to the trial's approved patient protocols.

27. Additionally, Medicaid Part A contains a hospital insurance program which provides coverage for hospital inpatients. Under Medicare Part A, the reimbursement decision is based upon an admitting diagnosis code, or the Diagnosis Related Group code ("DRG"). Medicare Part B pays bundled fees known as APCs under its Ambulatory Surgical Center Payment System (applicable to surgical centers that are not affiliated with hospitals) and Hospital Outpatient Prospective Payment System (applicable to hospitals). 74 Federal Register 60315 (Nov. 20, 2009).

28. Example DRG listings for hospital inpatient procedures using St. Jude cardiovascular access devices include, but are not limited to-

Medicare DRG Code	Description	Note
DRG 115	Permanent Cardiac Pacemaker Implant With Acute Myocardial Infarction, Heart Failure Or Shock, Or Acid Lead Or Generator Procedure	DRG code no longer valid after October 1, 2005
DRG 233	Coronary bypass with cardiac catheterization with Major Complication/Comorbid Conditions	DRG code not valid before October, 2007
DRG 234	Coronary bypass with cardiac catheterization without Major Complication/Comorbid Conditions	DRG code not valid before October, 2007
DRG 286	Circulatory disorders except Acute Myocardial infarction with cardiac catheterization with Major Complication/Comorbid Conditions	DRG code not valid before October, 2007
DRG 515	Cardiac Defibrillator Implant without Cardiac Catheter	DRG code no longer valid after October 1, 2007
DRG 516	Percutaneous cardiovascular procedures with acute myocardial infarction (AMI)	DRG code no longer valid after October 1, 2007
DRG 517	Percutaneous cardiovascular procedures without acute myocardial infarction (AMI),with coronary artery stent/DES implant	DRG code no longer valid after October 1, 2007

DRG 518	Percutaneous cardiovascular procedures without acute myocardial infarction (AMI),without coronary artery stent implant	DRG code no longer valid after October 1, 2007
DRG 535	Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial infarction, Heart Failure or Shock	DRG code no longer valid after October 1, 2007
DRG 536	Cardiac Defibillator Implant with Cardiac Catheterization without Acute Myocardial Infarction, Heart Failure or Shock	DRG code no longer valid after October 1, 2007

29. Additionally, provided below are estimated DRG payment amounts for some of the above listed procedures for those hospitals during the years 2005 through 2008. These estimates were calculated by using the "Inpatient PPS PC Pricer" payment program, made available to the public from the Centers for Medicaid and Medicare Services, available at http://www.cms.gov/ PCPricer/03_inpatient.asp. Medicare DRG code numbers and payments change annually, and changed significantly in 2007.

October 2005 / September 2006:

USC University Hospital
- DRG 515 - $44,391.73
- DRG 518 - $13,303.45
- DRG 535 - $64,119.33
- DRG 536 - $55,600.43

Santa Barbara Cottage Hospital
- DRG 515 - $36,029.95
- DRG 518 - $10,823.19
- DRG 535 - $52,025.33
- DRG 536 - $43,118.10

October 2006 / September 2007:

USC University Hospital
- DRG 515 - $42,658.76
- DRG 518 - $13,368.74
- DRG 535 - $60,155.26
- DRG 536 - $53,875.51

Santa Barbara Cottage Hospital
- DRG 515 - $34,324.75
- DRG 518 - $10,785.77
- DRG 535 - $48,385.86
- DRG 536 - $43,339.12

October 2007/ September 2008:

USC University Hospital
- DRG 233 - $52,161.70
- DRG 234 - $39,803.87
- DRG 286 - $13,479.57
- DRG 287 - $9,229.55

Santa Barbara Cottage Hospital
- DRG 233 - $40,560.98
- DRG 234 - $30,951.52
- DRG 286 - $10,481.73
- DRG 287 - $7,176.91

30. Medicare Part B also makes traditional fee-for-service payments to physicians. The fee-for-services charges of physicians under Medicare Part B are billed to Medicare on the form CMS 1500. This form requires an itemization of procedure and device charges using HCPC-1 and II codes. Medicare Part B is different from Part A because physician claims submitted on the CMS 1500 form entail an express certification of medical reasonableness and necessity on the reverse side of the form. That certification states: I certify that the services shown on this form were medically indicated and necessary for the health of the patient. Medicare should not make payment for items or services not reasonable and necessary for diagnosis or treatment. 42 U.S.C. 1395(a)(1)(A).

31. APC fees are different from DRG fees in that they are based upon HCPC-1 codes describing particular medical procedures, whereas DRG payments are based upon diagnostic codes describing only a disease, condition, or symptoms to be treated. Both the APC and DRG systems operate based upon claims submitted by the hospital or surgery center using form CMS 1450 (a/k/a Form UB-40). This form requires the facility to provide, among many other things, (1) the patient's diagnosis using the ICD-9 code that describes the disease, condition, or symptom for which the patient was treated, (2) HCPC codes for all items billed, (3) the facility's covered charges, and (4) the facility's non-covered charges. The non-covered charges are supposed to be reported in a separate column on the form.

32. The difference in reimbursement rules under Medicare parts A and B is that APC reimbursements under Medicare Part B are based on HCPC-1 codes describing particular medical procedures, whereas DRG payments under Medicare Part A are based upon ICD-9 diagnostic codes describing only a disease, condition, or symptom to be treated. The claims made pursuant to CMS 1450 forms do not involve the same certifications of medical necessity as

found on CMS 1500 forms. The relevant certification found on the reverse side of the form 1450 states: Submission of this claim constitutes certification that the billing information shown on the face hereof is true, accurate, and complete.

33. If coverage for a device is excluded, Medicare also excludes coverage for "medical and hospital services that are related to the use of a device." 43 C.F.R 405.207. These noncovered services include "all services furnished in preparation for the use of a noncovered device, services furnished contemporaneously with and necessary to the use of a noncovered device, and services furnished as necessary after-care that are incident to recovery from the use of the device or from receiving related noncovered services." *Id.*

34. The fact that surgery centers and hospitals received reimbursement payments for services and devices for which they did not actually pay meant that certifications pursuant to CMS forms 1450 and 1500 were false and caused improper payment from the government's health care programs.

C. The Devices at Issue in This Case

35. In his capacity as regional manager with St. Jude, Mr. Tun oversaw the vascular closure devices division, which dealt mainly with Class II devices used to close artery puncture wounds after the insertion of catheters. Relator's team of sales representatives sold St. Jude cardiology products like the Angio-Seal STS and STS Plus, Venture wire control catheters, Proxis, Livewire steerable catheters, SpyGlass catheters, and the Premere PFO closure system.

36. The AngioSeal™ STS Plus vascular closure device is a successor to the Angio-Seal Hemostatic Puncture Closure Device, which was approved by the FDA through the PMA process (PMA No. P930038) in September 1996. The Angio-Seal™ STS is indicated for use in closing and reducing time to hemostasis at the femoral arterial puncture site in patients who have

undergone diagnostic angiography procedures or interventional procedures using an 8 French or smaller or 6 French or smaller procedural sheath. The Angio-Seal device is also indicated for use to allow patients who have undergone diagnostic angiography or an interventional procedure to ambulate safely as soon as possible after sheath removal and device placement.

37. The Proxis System (Proximal Embolic Protection Device) is a Class II device indicated for use to prevent distal release of and to aspirate embolic material in saphenous vein coronary bypass grafts during percutaneous transluminal coronary angioplasty and/or stenting procedures. The Proxis System is also indicated to control the flow of fluids in the coronary and peripheral vasculature. The Proxis System was approved for use by the FDA in about January 2005 as being substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976.

38. St. Jude's Spyglass™ Angiographic Catheter is a fixed-curve catheter that is indicated for the delivery of radiopaque contrast media during angiographic procedures. St. Jude's LiveWire™ TC Compass Catheter is indicated for use in cardiac electrophysical mapping and for use with a compatible rf generator for interruption of accessory atrioventricular conduction pathways associated with tachycardia; the treatment of atrioventricular nodal re-entrant tachycardia; or creation of complete atrioventricular nodal block in patients with a difficult to control ventricular response to an atrial arrhythmia. St. Jude's Venture™ Wire Control Catheter is a Class II catheter indicated for directing, steering, controlling, and supporting a guide wire to access discrete regions of the coronary and peripheral vasculature. The original Venture™ Wire Control Catheter was approved by the FDA on Nov. 11, 2004.

39. The Premere™ patent foramen ovale closure system is designed to seal an incomplete closure of the atrial septum that results in the creation of a flap or a valve-like

opening in the atrial septal wall. The Stasys Patch (also known as HemaDerm) is a hemostatic patch used to stop bleeding during surgery, including in arterial wounds.

40. As set forth above, Mr. Tun's division also coordinated with St. Jude's CRM unit to promote St. Jude ICDs and cardiac resynchronization therapy devices (CRT-Ds). ICDs are designed to treat people suffering from abnormally fast heart rates (tachycardia). ICD devices detect abnormally fast heart rhythms, administering a mild shock (cardioversion) or an extreme shock (when necessary) to restore the heart's beating pattern to a normal rhythm. Cardiac resynchronization therapy devices (CRT-Ds) are designed to treat people suffering from a condition in which the lower chambers of the heart beat at different rates (ventricular dysynchrony) and heart failure. Cardiac resynchronization therapy devices (CRT-Ds) are known in the industry as "Bi-Vs," because they have a lead into each of the valves of the heart.

41. St. Jude's Epic, Epic Plus, Atlas, and Atlas Plus are ICDs with cardiac resynchronization therapy device (CRT-D) capabilities. They were approved for use in about June 2004 to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Both the Epic and Atlas systems are also approved for use to reduce symptoms of moderate to severe heart failure (nyha functional class iii or iv) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction less than or equal to 35% and a prolonged qrs duration.

42. St. Jude's Contour ICD is a descendant of St. Jude's Cadence ICD, which was approved for use in about 1993. The Contour ICD is also approved for use to reduce symptoms of moderate to severe heart failure (nyha functional class iii or iv) in those patients who remain

symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction less than or equal to 35%.

D. St. Jude Improperly Proffered Kickbacks to Hospitals and Physicians to Encourage the Use of St. Jude Devices

1. The Federal Anti-Kickback Statute

43. The Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts the medical decision-making process and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The AKS was enacted in 1972 to "provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

44. In 1977, Congress amended the AKS to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. See Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the anti-kickback statute was to combat fraud and abuse in medical settings, which:

> [C]heats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health

> services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs.

H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.

45. In 1987, Congress again strengthened the AKS to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. See Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

46. The AKS prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

The statute provides, in pertinent part:

> [W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
> 42 U.S.C. § 1320a-7b(b).

47. "Kickbacks" have been defined as including payments, gratuities, and other benefits paid to physicians who use medical devices by the manufacturers of the devices.

48. In addition to criminal penalties, a violation of the AKS can also subject the perpetrator to exclusion from participation in federal health care programs, 42 U.S.C. § 1320a-7(b)(7), as well as civil monetary penalties of $50,000 per violation, 42 U.S.C. § 1320a-7a(a)(7),

and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

49. In May 2003, the Inspector General of HHS published further guidance on marketing practices which may constitute kickbacks, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003) ("OIG Guidelines"). The OIG Guidelines address, among other things, the conflicts that may arise when a pharmaceutical manufacturer provides educational or research funding to "entities in a position to make or influence referrals." As a general rule, grants to physicians should be made without conditions or restrictions, otherwise the arrangement becomes a forbidden quid pro quo relationship: "Manufacturers should take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence the content of the program." *Id.* at § II (b)(2).

50. The AKS not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a medical device manufacturer to a physician that has as one of its purposes inducement of the physician to implant one of the medical device manufacturer's devices.

51. Compliance with the AKS is a precondition to participation as a health care provider under the federally-funded healthcare programs and the state Medicaid programs. Indeed, compliance with the AKS is a condition of payment for claims for which Medicare or Medicaid reimbursement is sought by medical providers.

2. St. Jude Violated the Anti-Kickback Statute by Using Illegal Inducements

a. Referral Dinners

52. St. Jude illegally induced physicians and other health care providers across the country to utilize its vascular closure devices by paying illegal kickbacks. One way in which St.

Jude executed its illegal kickback scheme was by paying implanting physicians to speak at expensive referral dinners events held at lavish restaurants. Physicians often referred patients for medical device implants to cardiac surgeons and cardiologists who performed surgeries and procedures. Referral dinners were an opportunity for St. Jude to give two inducements to high device using physicians; the first to pay them to speak to their colleagues and referral sources, and the second to pay for expensive dinners and drinks for those industry contacts.

53. The inducements were only given to physicians who used or caused the use of St. Jude devices in high numbers, as the company directly took into account the volume and value of the business generated when seeking out physicians for hire. For example, part of the February 7, 2005 St. Jude sales plan for Riverside Methodist Hospital in Columbus, Ohio, was to conduct heart failure symposia for referring physicians in an effort to help achieve a 26% revenue growth over the prior year's sales. By spending money on and organizing referral dinners, St. Jude in effect created a valuable inducement of generating referral business for the hospital.

54. Another St. Jude April 27, 2005 sales plan for Fountain Valley Regional Hospital evidences the arrangement of a referral dinner for Dr. Thuy Le in order to achieve 33% revenue growth over the prior year's sales. A similar sales plan called for a dinner and St. Jude medical device technology fair in order to achieve 39% revenue growth over the prior year's sales at Anaheim Memorial Hospital. Part of the April 28, 2005 St. Jude sales plan for Eisenhower Medical Center in Rancho Mirage was again to set up a referral dinner in order to achieve 49% revenue growth over the prior year's sales.

55. A St. Jude October 26, 2005 sales strategy document titled "Regional Review" notes that St. Jude sales suffered a loss of $32,040 in revenue and 90 units of Angio-Seal sold at USC University Hospital. In order to remedy the problem, St. Jude held a dinner in order to

"increase utilization of AS (Angio-Seal)." A similar November 3, 2005 sales strategy document titled "Down Accounts" noted that the St. Jude experienced a loss of $27,809 in revenue at USC University. The same document noted a scheduled dinner for the "Fellows" in order to "increase utilization of AS (Angio-Seal)."

56. A June 25, 2005 sales document called "Low Accounts" reveals that St. Jude sales representative Jim Coscia was attempting to reverse a downward trend of $34,500 in revenues and a loss of 150 unit sales of VSD products from LA County USC health clinics and at USC University Hospital by holding "Fellows dinners."

57. St. Jude not only paid for every attending physicians' meal and alcoholic beverages at the dinners, the company additionally spent between $1500 to $2000 for implanting physicians to speak to colleagues at these events. In this way, St. Jude allowed implanting physicians to gain larger referral numbers by spending thousands of dollars in promotional fees to stage elaborate dinner parties.

58. Sales representatives were trained and furthermore required to offer these inducements in the form of kickbacks to physicians. A 2005 St. Jude sales strategy document titled "Matt Kessler Venture Plan" reveals that sales representatives were pushing to have Venture catheters in use at Sunrise Hospital in Las Vegas by "trying to get the Dr's [sic] who go there out to dinner."

59. A similar March 3, 2005 St. Jude performance improvement plan for sales representative Beth Guich requires her to arrange two dinners for physicians at Huntington Memorial Hospital and at Antelope Valley Hospital within a two month period. If Beth Guich failed to run the dinners and failed to target her "highest potential accounts," she would face disciplinary action and possibly termination. The disciplinary action was approved by Relator's